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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/751,043 | 01/02/2004 | Syed F.A. Hossainy | 50623.362 | 1927 |

7590 05/01/2008
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| EXAMINER |
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GEORGE, KONATA M

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| ART UNIT | PAPER NUMBER |
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1616

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| MAIL DATE | DELIVERY MODE |
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05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/751,043 | Applicant(s) HOSSAINY ET AL. | |
| | Examiner KONATA M. GEORGE | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-43, 46 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-43, 46 and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 37-43, 46 and 48-52 are pending in this application.

Request for Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2008 has been entered.

Action Summary

The rejection of claims 37-43, 46 and 48-52 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn as applicant has amended the claims to overcome the rejection.

The rejection of claims 37-39, 41-43, 46 and 48-52 under 35 U.S.C. 102(e) as being anticipated by Ding is being maintained for the reasons stated in the office action dated March 30, 2007.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 37-39, 41-43, 46 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding (US 6,652,581).

Ding discloses a method of curing a composition onto a device (col. 5, lines 5-18). The method evaporates the solvent by heating at approximately 90°C or as high as 150°C (depending on the polymer, drug and solvents used). Column 3, lines 19-20 teach the device including self-expanding stents and balloon expandable stents; lines 33-35 teach the device can be made from polymeric, ceramic, metallic or composite materials. Column 4, lines 1-26 teach examples of the polymers that can be employed in the composition. Column 7, lines 1-21 teach the use of drugs in the composition.

Response to Arguments

Applicant's arguments filed March 19, 2008 have been fully considered but they are not persuasive.

Applicant argues that Ding does not teach that the temperature is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer. The examiner disagrees. As mentioned above, the composition is heated to a temperature from about 90°-150°C (depending on the polymer, drug and solvents used). Column 4, lines 1-26 teach polymers that can be used in the composition. It is the position of the examiner that the limitation of the temperature is met by some of the polymers listed. For example, polyvinyl chloride has a glass transition temperature of 87°C and a melting point temperature of 212°C; polystyrene has a glass transition temperature of 95°C and a melting point temperature of 240°C. As can be seen from these two examples, the temperature of the polymers of Ding is above the glass transition temperature and below the melting point temperature.

Applicants argue that although some of the polymers fall within the scope of the invention, this rational, is a clear example of "i.e. picking the right polymer". The examiner disagrees. Examples of the polymers that fall within temperature ranges (i.e. wherein the glass transition temperature of the polymer is below the melting temperature of the polymer) are well known polymers (i.e. polystyrene and polyvinyl chloride) that are widely used in coating stents. So one would not necessary be "picking the right polymer" since it is widely used. Furthermore, one of ordinary skill in the art when applying a coating onto a stent in the manner described by applicant would take into consideration the melting point of the polymer so that the polymer would not be broken down during the production process. One or ordinary skill in the art would not

want to reach the melting point of the polymer, as it would destroy the integrity of the polymer.

The rejection of claims 37-43, 46 and 48-52 under 35 U.S.C. 103(a) as being unpatentable over Ding is being maintained for the reasons stated in the office action dated March 30, 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37-443 46 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 6,652,581).

Applicant claims a method of forming a coating for an implantable device comprising applying a composition including a solvent and a polymer to the device, heating the composition to a temperature that is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer.

***Determination of the scope and content of the prior art
(MPEP §2141.01)***

Ding discloses a method of curing a composition onto a device (col. 5, lines 5-18). The method evaporates the solvent by heating at approximately 90°C or as high as 150°C (depending on the polymer, drug and solvents used). Column 3, lines 19-20

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teach the device including self-expanding stents and balloon expandable stents; lines 33-35 teach the device can be made from polymeric, ceramic, metallic or composite materials. Column 4, lines 1-26 teach examples of the polymers that can be employed in the composition. Column 7, lines 1-21 teach the use of drugs in the composition.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

Ding does not teach that the polymer and solvent composition is drug free.

***Finding of prima facie obviousness
Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the composition without the use of a drug. It would have been within reason for one of ordinary skill not to add a drug to the coating formulation for the purposes of coating a device (i.e. stent or balloon expandable stents) whose primary purpose is to open the blood vessel and/or keep the blood vessel open, and where drug delivery is not necessary.

Response to Arguments

Applicant's arguments filed March 19, 2008 have been fully considered but they are not persuasive.

Applicant argues that Ding does not teach that the temperature is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer. The examiner disagrees. As mentioned above, the composition is heated to a temperature from about 90° to 150°C (depending on the polymer, drug and solvents used). Column 4, lines 1-26 teach polymers that can be used in the composition. It is the position of the examiner that the limitation of the temperature is met by some of the polymers listed, for example, polyvinyl chloride has a glass transition temperature of 87°C and a melting point temperature of 212°C; polystyrene has a glass transition temperature of 95°C and a melting point temperature of 240°C. As you can see from these two examples, the temperature of the polymers of Ding is above the glass transition temperature and below the melting point temperature

Applicants argue that although some of the polymers fall within the scope of the invention, this rational, is a clear example of "i.e. picking the right polymer". The examiner disagrees. Examples of the polymers that fall within temperature ranges are well known polymers (i.e. polystyrene and polyvinyl chloride) that are widely used in coating stents. So one would not necessary be "picking the right polymer" since it is widely used as a coating for stents. Furthermore, one of ordinary skill in the art is applying a coating onto a stent in the manner described by applicant the melting point of the polymer would be taken into consideration. One of ordinary skill in the art would not want to reach the melting point of the polymer, as it would destroy the integrity of the polymer.

Conclusion

Claims 37-43, 46 and 48-52 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616

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|
/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616